

Objectives

- Review regulations and biosafety levels
- JSC Biosafety Facilities
- Biosafety cabinet usage and maintenance
- Exposure and Spill Clean-up
- Training requirements





Biosafety Regulations

 NASA Procedural Requirements (NPR) 1800: NASA Occupational Health Program Procedures, Section 4.1.1 Biosafety - mandates compliance with CDC BMBL, ICAO, IATA

Acronyms

ABSA – American Biological Safety Association

CDC- Centers for Disease Control

BMBL - Biosafety in Microbiological and Biomedical Laboratories

GAO - Government Accountability Office

CAO - International Civil Aviation Organization

HHS - Health and Human Services

IATA- International Air Transport Association

NIH - National Institutes for Health

USDA - United States Department of Agriculture

WHO - World Health Organization







National Actions Subcommittee on Oversight and Investigations October, 2007

- American Society for Microbiology :
 - Need to ensure adequate biosafety training
 - ☐ Strict Compliance with NIH Guidelines and BMBL (CDC/NIH)
- GAO report called for:
 - ☐ Train lab staff in general biosafety
- NIH and CDC Testimony:
 - □ Establishment of a Trans-Federal Task Force on Optimizing Biosafety Oversight, consisting of representatives of a broad range of Federal agencies concerned with biosafety risks
 - ☐ Biosafety Curriculum Development and Biosafety Training
 - ☐ Individuals with Certification
 - Institutions with Accreditation







- CDC/NIH Biosafety in Microbiological and Biomedical Laboratories
- NIH Guidelines for Research Involving Recombinant DNA Molecules
- OSHA Bloodborne Pathogen Standard
- ICAO/IATA/DOT Transportation of Hazardous Materials





Select Agent Regulations

- Since September 11, 2001, two major pieces of legislation, the USA PATRIOT Act of 2001 and the "Public Health Security and Bioterrorism Preparedness Act of 2002" have changed the law governing the possession, use, and transport of etiologic agents.
- A current list of select agents and other updates may be found at the CDC Office of the Director Select Agent Program website, http://www.cdc.gov/od/sap/index.htm.
- Civil penalties for violating the regulations may amount to \$250,000 for an individual.
- Criminal penalties include a fine or imprisonment up to five years for possession without registration or transfer of a select agent to an unregistered individual.







- Select Agents
 - Microorganisms and toxins that have the potential to pose a severe threat to public health (humans, animals, and plants) and safety.
 - The use and transfer of select agents is regulated by HHS and USDA.
 - 1) HHS SELECT AGENTS AND TOXINS
 - Yersinia pestis, Ricin
 - 2) USDA SELECT AGENTS AND TOXINS
 - Foot-and-mouth disease virus
 - 3) USDA PLANT PROTECTION AND QUARANTINE SELECT AGENTS AND TOXINS



Genetically Modified Materials

- NIH Guidelines for Research Involving Recombinant DNA Molecules
- JSC Biosafety Review Board Form 644







Area Specific Plans -

OMOHC Tuberculosis exposure control plan, Wyle BBP Program and Wyle Chemical Hygiene Plan

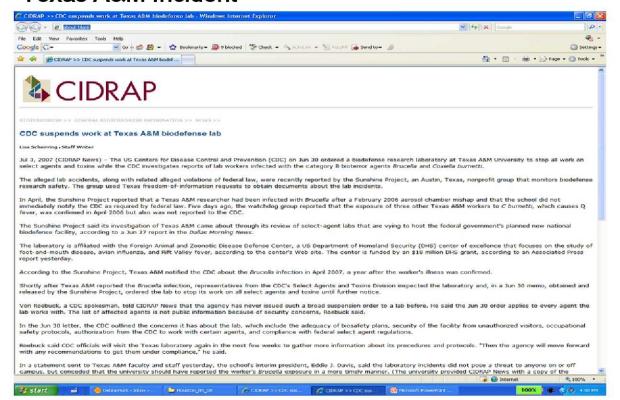
For links to the national and international guidelines and regulations - http://www.absa.org

Under resources and tools - Key topics and links



How Does Biosafety Impact Us?

- Career Suspension of Work
 - Texas A&M Incident









How Does Biosafety Impact Us?

- Personal
 - Texas Tech Incident
 - Thomas Butler, an infectious disease specialist was arrested and jailed in 2003 for the "mis-handling" of Select Agents.
 - Elizabeth Griffin Research Foundation
 - In 1997, Beth Griffin, a research technician at Emory University, died after contracting B-virus as a result of inadequate prevention procedures and deficient treatment after exposure.





Biosafety at JSC

 Biosafety Review Board- The mission of the Biosafety Review Board (BRB) is to identify, evaluate, control and prevent biological hazards in conformance with NASA, Federal and international health and safety regulations.

http://hefd.jsc.nasa.gov/microbrb.htm

- The BRB includes a team of microbiologists, cell biologists, physicians, industrial hygienists, and occupational health professionals to assess the wide range of biohazardous materials encountered.
- Biohazardous materials may consist of bacteria, fungi, viruses, protozoa, cell cultures, and other infectious agents.





Functions of the JSC BRB

- Operations provide assessments of flight operations regarding biosafety and potential exposure to crew-members
- Research All biological materials for use in JSC facilities are reviewed and approved prior to purchase.
- Payloads All biological payloads are assessed and biohazardous materials identified are assigned a NASA biosafety level (BSL).







Additional Functions of the BRB

- Conduct annual inspection of laboratories at JSC that utilize biological materials.
- Train personnel in policies and procedures of transporting biological materials.
- Maintain inventory of biological materials that are used at JSC including select agents (SA) and genetically modified materials (GMO)
- Investigate incidents that involved biological materials.
- Obtain Transportation Security Administration exemptions for hand-carrying of crew specimens.







JSC Biosafety Review Board (BRB) Members

- Microbiology D. L. Pierson Chair
- Microbiology Mark Ott
- Microbiology Wing C. Wong
- Occupational Health Sean Keprta
- Occupational Health Robert Martel
- Clinical Kathleen McMonigal
- Clinical Reta Warren
- Safety Wyle Tom Samson
- Cell Biology Neal Pellis
- Cell Biology Tom Goodwin
- Radiation Honglu Wu
- Environmental Factors Bob Spann
- Astromaterials Carl Allen
- Biosafety Dee Zimmerman UTMB/Health & Safety
- Biosafety Debra Hunt Duke University
- Administrative Specialist Sharon Jackson





Biosafety Review Board

Biohazardous Materials Approval Form		
To be completed by requesting organization (all requested information must be typed):		
1. Name, title and affiliation:	2. Address (building, room number, telephone number):	
3. Description of biohazardous material:		
4. Origin of biohazardous material:		
5a. List any potential hazards to personnel:		
5b. Are humans susceptible to infection by this organ Is medical surveillance required/recommended? Y		
5c. Is immunization required/recommended? Yes □	No 🗀 🗆 🗆	
6. Project location: Building(s) and room number(s)	to be used for storage, analysis, and disposal:	
Name(s) of personnel (scientists) handling material	s: 8. List all other biological research projects that may be involved with this project and may present a risk of cross-contamination:	
9. Describe procedures on attached pages:		
10. Will animals be used? Yes □No □ If yes, please	explain. (Status of JSC ACUC Approval)	
11. Will this project utilize any type of regulated radi Radiation User Approval)	ation? Yes □No □□□If yes, please explain. (Status of JSC	
12. Name/telephone number of NASA Technical Monitor:	13. Name/telephone number of Contract Laboratory Supervisor	
Signature and date:	Signature and date:	
To be completed by JSC Biosafety Review B	oard:	
Approved/Disapproved:		
Comments:		
(Typed Name and Telephone Number of Chairperson	Date	

1. Principal Investigator Name, title and affiliation: 2. Address (building, room number, telephone and fax number): 3a. Name of experiment: 3b. Name and Acronym of Payload (if different than the name of the experiment in 3a): 4. Experiment Number and Acronym (If applicable): 5a. Shuttle Mission Number: 5b. International Space Station Expedition Number: 6a. Launch vehicle: 6b. Launch date: 7a. Return vehicle: 7b. Return date: 8. In-flight Storage Location: 9. In-flight Use Location: International Partner Concurrence: International Partner Concurrence: International Partner Concurrence: Yes No Not applicable Yes No Not applicable 10. Please attach a detailed description of the experimental protocol. Follow the checklist (A-H) provided below. Answer each letter in the checklist as thoroughly as possible. Checklist: (to be completed for data submittal) A. Provide the identification and origin of biological material. B. Indicate if the biological materials (e.g., microbiological agents, animals and plants) are human pathogens or contain pathogens. C. Indicate the American Type Culture Collection number (ATCC#), if known. D. Indicate if cell cultures of human origin are free of Hepatitis A, B, C, HTLV 1& 2 and HIV 1&2. E. Indicate the maximum number of samples. I. Indicate the maximum number of samples. H. Indicate the maximum nu	Items 1-15 are to be completed by requesting of	organization (Must be typed):
3a. Name of experiment: 3b. Name and Acronym of Payload (if different than the name of the experiment in 3a): 4. Experiment Number and Acronym (If applicable): 5a. Shuttle Mission Number: 5b. International Space Station Expedition Number: 6a. Launch vehicle: 6b. Launch date: 7b. Return date: 8. In-flight Storage Location: International Partner Concurrence: International Partner Concurrence: International Partner Concurrence: Yes	1. Principal Investigator Name, title and affiliation:	
3b. Name and Acronym of Payload (if different than the name of the experiment in 3a): 4. Experiment Number and Acronym (If applicable): 5a. Shuttle Mission Number: 5b. International Space Station Expedition Number: 6a. Launch vehicle: 6b. Launch date: 7b. Return date: 8. In-flight Storage Location: International Partner Concurrence: Yes No Not applicable Partner Concurrence: Yes No Not applicable Not applicable Partner Concurrence: Yes No Not applicable Partner Concurrence: Orease attach a detailed description of the experimental protocol. Follow the checklist (A-II) provided below. Answer each letter in the checklist as thoroughly as possible. Checklist: (to be completed for data submittal) A. Provide the identification and origin of biological material. B. Indicate if the biological materials (e.g., microbiological agents, animals and plants) are human pathogens or contain pathogens. C. Indicate the American Type Culture Collection number (ATCC#), if known. D. Indicate the Biosafety Level (BSL), if known. G. Indicate the Biosafety Level (BSL), if known. G. Indicate the maximum number of samples. H. Indicate the maximum amount of microbiological agents per sample and the subsystem (i.e. vial, bag, syringe tray, canister, etc. NOTE: ** Hems A and B are intended to be answered using a thorough description. ** Hems C thru H can be answered in a table format for simplicity (see attached sample table for		0
4. Experiment Number and Acronym (If applicable): 5a. Shuttle Mission Number: 5b. International Space Station Expedition Number: 6a. Launch vehicle: 6b. Launch date: 7b. Return date: 9. In-flight Use Location: International Partner Concurrence: International Partner Concurrence: International Partner Concurrence: Yes	3a. Name of experiment:	- 2
5a. Shuttle Mission Number: 5b. International Space Station Expedition Number: 6a. Launch vehicle: 6b. Launch date: 7a. Return vehicle: 7b. Return date: 8. In-flight Storage Location: International Partner Concurrence: □ International Partner Concurrence: □ Int	3b. Name and Acronym of Payload (if different than th	e name of the experiment in 3a):
5b. International Space Station Expedition Number: 6a. Launch vehicle: 6b. Launch date: 7b. Return date: 7 b. Return date: 9. In-flight Use Location: International Partner Concurrence: International Partner Concurrence: International Partner Concurrence: International Partner Concurrence: International Partner Concurrence: International Partner Concurrence: International Partner Concurrence	4. Experiment Number and Acronym (If applicable):	
6a. Launch vehicle: 7b. Return date: 7c. Return vehicle: 7b. Return date: 8. In-flight Storage Location: International Partner Concurrence: Yes	5a. Shuttle Mission Number:	
6a. Launch vehicle: 7b. Return date: 7c. Return vehicle: 7b. Return date: 8. In-flight Storage Location: International Partner Concurrence: Yes		
7a. Return vehicle: 7b. Return date: 8. In-flight Storage Location: 9. In-flight Use Location: International Partner Concurrence: □ International Partner Co	5b. International Space Station Expedition Number:	
8. In-flight Storage Location: International Partner Concurrence: □Yes □No □Not applicable □Yes □No □Not applicable□ 10. Please attach a detailed description of the experimental protocol. Follow the checklist (A-H) provided below. Answer each letter in the checklist as thoroughly as possible. Checklist: (to be completed for data submittal) A. Provide the identification and origin of biological material. B. Indicate if the biological materials (e.g., microbiological agents, animals and plants) are human pathogens or contain pathogens. C. Indicate the American Type Culture Collection number (ATCC#), if known. D. Indicate if cell cultures of human origin are free of Hepatitis A, B, C, HTLV 1& 2 and HIV 1&2. E. Indicate the Biosafety Level (BSL), if known. G. Indicate the maximum mumber of samples. H. Indicate the maximum amount of microbiological agents per sample and the subsystem (i.e. vial, bag, syringe tray, canister, etc. NOTE: ** Hems A and B are intended to be answered using a thorough description. ** Items C thru H can be answered in a table format for simplicity (see attached sample table for	6a. Launch vehicle:	6b. Launch date:
8. In-flight Storage Location: International Partner Concurrence: □Yes □No □Not applicable □Yes □No □Not applicable□ 10. Please attach a detailed description of the experimental protocol. Follow the checklist (A-H) provided below. Answer each letter in the checklist as thoroughly as possible. Checklist: (to be completed for data submittal) A. Provide the identification and origin of biological material. B. Indicate if the biological materials (e.g., microbiological agents, animals and plants) are human pathogens or contain pathogens. C. Indicate the American Type Culture Collection number (ATCC#), if known. D. Indicate if cell cultures of human origin are free of Hepatitis A, B, C, HTLV 1& 2 and HIV 1&2. E. Indicate the Biosafety Level (BSL), if known. G. Indicate the maximum amount of microbiological agents per sample and the subsystem (i.e. vial, bag, syringe tray, canister, etc. NOTE: ** Hems A and B are intended to be answered using a thorough description. ** Items C thru H can be answered in a table format for simplicity (see attached sample table for		
International Partner Concurrence: □Yes □No □Not applicable □Yes □No □Not applicable□ 10. Please attach a detailed description of the experimental protocol. Follow the checklist (A-H) provided below. Answer each letter in the checklist as thoroughly as possible. Checklist: (to be completed for data submittal) A. Provide the identification and origin of biological material. B. Indicate if the biological materials (e.g., microbiological agents, animals and plants) are human pathogens or contain pathogens. C. Indicate the American Type Culture Collection number (ATCC#), if known. D. Indicate the Gell cultures of human origin are free of Hepatitis A, B, C, HTLV 1& 2 and HIV 1&2. E. Indicate the maximum concentration of each sample. F. Indicate the maximum number of samples. H. Indicate the maximum number of samples. H. Indicate the maximum number of samples. H. Indicate the maximum amount of microbiological agents per sample and the subsystem (i.e. vial, bag, syringe tray, canister, etc. NOTE: ** Items A and B are intended to be answered using a thorough description. ** Items C thru H can be answered in a table format for simplicity (see attached sample table for	7a. Return vehicle:	7b. Return date:
Yes	8. In-flight Storage Location:	9. In-flight Use Location:
10. Please attach a detailed description of the experimental protocol. Follow the checklist (A-H) provided below. Answer each letter in the checklist as thoroughly as possible. Checklist: (to be completed for data submittal) A. Provide the identification and origin of biological material. B. Indicate if the biological materials (e.g., microbiological agents, animals and plants) are human pathogens or contain pathogens. C. Indicate the American Type Culture Collection number (ATCC#), if known. D. Indicate if cell cultures of human origin are free of Hepatitis A, B, C, HTLV 1& 2 and HIV 1&2. E. Indicate the maximum concentration of each sample. F. Indicate the Biosafety Level (BSL), if known. G. Indicate the maximum number of samples. H. Indicate the maximum amount of microbiological agents per sample and the subsystem (i.e. vial, bag, syringe tray, canister, etc. NOTE: ** Items A and B are intended to be answered using a thorough description. ** Items C thru H can be answered in a table format for simplicity (see attached sample table for	International Partner Concurrence:	☐ International Partner Concurrence:
Follow the checklist (A-H) provided below. Answer each letter in the checklist as thoroughly as possible. Checklist: (to be completed for data submittal) A. Provide the identification and origin of biological material. B. Indicate if the biological materials (e.g., microbiological agents, animals and plants) are human pathogens or contain pathogens. C. Indicate the American Type Culture Collection number (ATCC#), if known. D. Indicate if cell cultures of human origin are free of Hepatitis A, B, C, HTLV 1& 2 and HIV 1&2. E. Indicate the maximum concentration of each sample. F. Indicate the Biosafety Level (BSL), if known. G. Indicate the maximum number of samples. H. Indicate the maximum amount of microbiological agents per sample and the subsystem (i.e. vial, bag, syringe tray, canister, etc. NOTE: ** Items A and B are intended to be answered using a thorough description. ** Items C thru H can be answered in a table format for simplicity (see attached sample table for	□Yes □No □Not applicable	□Yes □No □Not applicable□
Checklist: (to be completed for data submittal) A. Provide the identification and origin of biological material. B. Indicate if the biological materials (e.g., microbiological agents, animals and plants) are human pathogens or contain pathogens. C. Indicate the American Type Culture Collection number (ATCC#), if known. D. Indicate the Cultures of human origin are free of Hepatitis A, B, C, HTLV 1& 2 and HIV 1&2. E. Indicate the Biosafety Level (BSL), if known. G. Indicate the maximum number of samples. H. Indicate the maximum number of samples. H. Indicate the maximum amount of microbiological agents per sample and the subsystem (i.e. vial, bag, syringe tray, canister, etc. NOTE: ** Items A and B are intended to be answered using a thorough description. ** Items C thru H can be answered in a table format for simplicity (see attached sample table for		
 A. Provide the identification and origin of biological material. B. Indicate if the biological materials (e.g., microbiological agents, animals and plants) are human pathogens or contain pathogens. C. Indicate the American Type Culture Collection number (ATCC#), if known. D. Indicate if cell cultures of human origin are free of Hepatitis A, B, C, HTLV 1& 2 and HIV 1&2. E. Indicate the maximum concentration of each sample. F. Indicate the Biosafety Level (BSL), if known. G. Indicate the maximum number of samples. H. Indicate the maximum amount of microbiological agents per sample and the subsystem (i.e. vial, bag, syringe tray, canister, etc. NOTE: ** Items A and B are intended to be answered using a thorough description. ** Items C thru H can be answered in a table format for simplicity (see attached sample table for 	Follow the checklist (A-H) provided below. Answer	each letter in the checklist as thoroughly as possible.
B. Indicate if the biological materials (e.g., microbiological agents, animals and plants) are human pathogens or contain pathogens. C. Indicate the American Type Culture Collection number (ATCC#), if known. D. Indicate if cell cultures of human origin are free of Hepatitis A, B, C, HTLV 1& 2 and HIV 1&2. E. Indicate the maximum concentration of each sample. F. Indicate the Biosafety Level (BSL), if known. G. Indicate the maximum number of samples. H. Indicate the maximum amount of microbiological agents per sample and the subsystem (i.e. vial, bag, syringe tray, canister, etc. NOTE: ** Items A and B are intended to be answered using a thorough description. ** Items C thru H can be answered in a table format for simplicity (see attached sample table for	Checklist: (to be completed for data submittal)	
contain pathogens. C. Indicate the American Type Culture Collection number (ATCC#), if known. D. Indicate it cell cultures of human origin are free of Hepatitis A, B, C, HTLV 1& 2 and HIV 1&2. E. Indicate the maximum concentration of each sample. F. Indicate the Biosafety Level (BSL), if known. G. Indicate the maximum number of samples. H. Indicate the maximum amount of microbiological agents per sample and the subsystem (i.e. vial, bag, syringe tray, canister, etc. NOTE: ** Items A and B are intended to be answered using a thorough description. ** Items C thru H can be answered in a table format for simplicity (see attached sample table for		
C. Indicate the American Type Culture Collection number (ATCC#), if known. D. Indicate if cell cultures of human origin are free of Hepatitis A, B, C, HTLV 1& 2 and HIV 1&2. E. Indicate the maximum concentration of each sample. F. Indicate the Biosafety Level (BSL), if known. G. Indicate the maximum number of samples. H. Indicate the maximum amount of microbiological agents per sample and the subsystem (i.e. vial, bag, syringe tray, canister, etc. NOTE: ** Items A and B are intended to be answered using a thorough description. ** Items C thru H can be answered in a table format for simplicity (see attached sample table for		biological agents, animals and plants) are human pathogens or
D. Indicate if cell cultures of human origin are free of Hepatitis A, B, C, HTLV 1& 2 and HIV 1&2. E. Indicate the maximum concentration of each sample. F. Indicate the Biosafety Level (BSL), if known. G. Indicate the maximum number of samples. H. Indicate the maximum amount of microbiological agents per sample and the subsystem (i.e. vial, bag, syringe tray, canister, etc. NOTE: ** Items A and B are intended to be answered using a thorough description. ** Items C thru H can be answered in a table format for simplicity (see attached sample table for		on number (ATCC#) if known
E. Indicate the maximum concentration of each sample. F. Indicate the Biosafety Level (BSL), if known. G. Indicate the maximum number of samples. H. Indicate the maximum amount of microbiological agents per sample and the subsystem (i.e. vial, bag, syringe tray, canister, etc. NOTE: ** Items A and B are intended to be answered using a thorough description. ** Items C thru H can be answered in a table format for simplicity (see attached sample table for		
G. Indicate the maximum number of samples. H. Indicate the maximum amount of microbiological agents per sample and the subsystem (i.e. vial, bag, syringe tray, canister, etc. NOTE: ** Items A and B are intended to be answered using a thorough description. ** Items C thru H can be answered in a table format for simplicity (see attached sample table for		
 H. Indicate the maximum amount of microbiological agents per sample and the subsystem (i.e. vial, bag, syringe tray, canister, etc. NOTE: ** Items A and B are intended to be answered using a thorough description. ** Items C thru H can be answered in a table format for simplicity (see attached sample table for 	F. Indicate the Biosafety Level (BSL), if known.	
tray, canister, etc. NOTE: ** Items A and B are intended to be answered using a thorough description. ** Items C thru H can be answered in a table format for simplicity (see attached sample table for		
** Items A and B are intended to be answered using a thorough description. ** Items C thru H can be answered in a table format for simplicity (see attached sample table for		ical agents per sample and the subsystem (i.e. vial, bag, syringe,
** Items C thru H can be answered in a table format for simplicity (see attached sample table for	330	
	NOIE:	ing a thorough description.
	** Items A and B are intended to be answered usi	







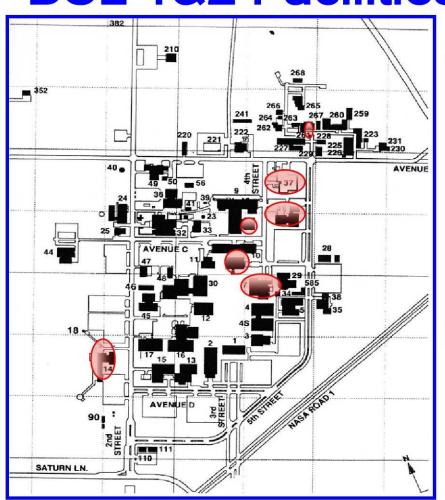
JSC Form 644







BSL 1&2 Facilities at JSC



B7 – Biological Process

B8 - Clinic

B9S - BDCF

B14 - BEEST

B31 – Astrobiology

B37 - SLSD Labs

B261 – Cardiovascular Lab





BSL 1&2 Facilities at JSC

B7 – Biological Process Development Facility

B8 – Clinical Laboratory – blood, urine

B9 - Baseline Data Collection - blood, tissue collection

B14 - BEEST - human cell lines/cultures

B31 – Astrobiology – nanobacteria

B261 - Cardiovascular Laboratory - blood







Microbiology -

Immunology -

Biosystems -

HACO-Core -

Clinical -

Pharmacology -

Radiation -

Muscle Research -

Nutritional Biochemistry -







Biosafety Training Requirements

 Computer-based training every 2 years - all personnel handling BSL 1 and 2 materials

Other related training-

- One-time JSC PPE course
- Annual BBP training all personnel handling potentially infectious materials JSC or Wyle
- Annual Shipping of Biologicals training personnel that ship Exempt Human Specimens - Wyle Bioastronautics
- Shipping of dry ice 2 years personnel who ship samples on dry ice - Wyle Bioastronautics
- Shipping of Infectious Substances 2 years personnel that ship infectious substances - Saf-T-Pak or other



Biosafety - Assessing the Risk

- What are you working with? and how much?
- What Risk Group is it in?
- Is it a Select Agent? GMO?
- Do you have BRB approval for use?
- Do you have the proper facilities, PPE, disinfectants, training, vaccinations?





Biosafety – Assessing the Risk

- Risk Groups (RG)
 - A classification of infectious microorganisms based on the following factors:
 - · Pathogenicity of the organism
 - Mode of transmission and host range
 - Availability of effective preventive measures (e.g., vaccines)
 - Availability of effective treatment (e.g., antibiotics)
 - Risk classification for World Health Organization, Australia, Canada, European Union, U.S.(NIH), and New Zealand:
 - Risk Group 1 (RG1) agents are not associated with disease in healthy adult humans. E. coli K-12
 - Risk Group 2 (RG2) agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available. S. typhimurium/C. neoformans/Hep. B
 - Risk Group 3 (RG3) agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available. Yersinia pestis/Histoplasma capsulatum/HIV





Biosafety - Assessing the Risks

- Biosafety Level (BSL)
 - Biosafety Containment Level, handling practices, facility design; not directly correlated to RG.
 - Used by CDC/NIH in "Biosafety in Microbiological and Biomedical Laboratories (BMBL)"

BSL-1 is suitable for work involving well-characterized agents not known to cause disease in healthy adult humans, and of minimal potential hazard to laboratory personnel and the environment.

BSL-2 is similar to Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment.

BSL-3 is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents which may cause serious or potentially lethal disease as a result of exposure by the inhalation route.

BSL-4 is required for work with dangerous and exotic agents which pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease.







- Currently, work at JSC is limited to BSL-1 and BSL-2 organisms.
- For complete list of bacterial, viral and fungal agents and their corresponding biosafety levels and risk groups, please visit http://www.absa.org/resriskgroup.html







(Route of transmission, pathogenicity, ID)



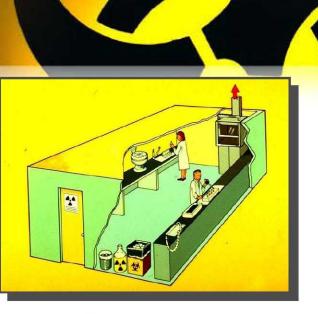
Microbiological Risk Assessment

(Procedures, concentrations, Rx, host, etc.)

Biosafety Level (BSL)







BSL-1 Lower Risk



BSL-2 / Universal Precautions





Biosafety - Assessing the Risk

BSL-2 differs from BSL-1:

- laboratory personnel have specific training in handling pathogenic agents and are directed by scientists with advanced training;
- access to the laboratory is limited when work is being conducted;
- extreme precautions are taken with contaminated sharp items; and
- certain procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.



Reducing the Risk

- Biological
 - Use Attenuated or less virulent strains
 - E. coli K-12
- Physical
 - Primary & secondary containment
 - Primary: physical separation of hazard from worker
 - PPE
 - Equipment (biological safety cabinets, enclosed centrifuge containers)
 - Secondary: lab design, separation of hazard from others in facility and the environment
 - Separate labs, unidirectional airflow
- Risk Assessments/Safe Microbiological Practices/Training/Vaccinations



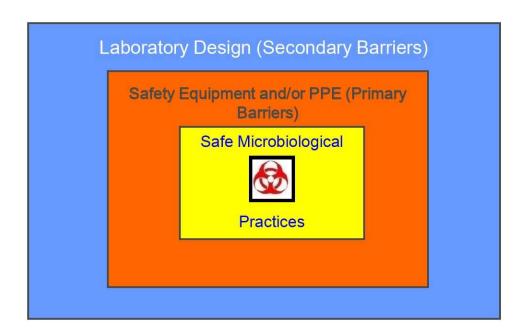


Containment

- Containment is used in describing safe methods for managing biological agents in the laboratory environment where they are being handled or maintained. The purpose of containment is to reduce or eliminate exposure of laboratory workers, persons outside the laboratory, and the environment to potentially hazardous agents.
- The three elements of containment include laboratory practice and technique, safety equipment, and facility design.
- The proper containment is located by identification of the risk group and the appropriate biosafety level.
- The biosafety levels consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities appropriate for the operations performed. They are also based on the potential hazards imposed by the agents used and for the laboratory function and activity.
- As a general rule, a biosafety level should be used that matches the highest Risk Group (RG) classification of the organism involved.



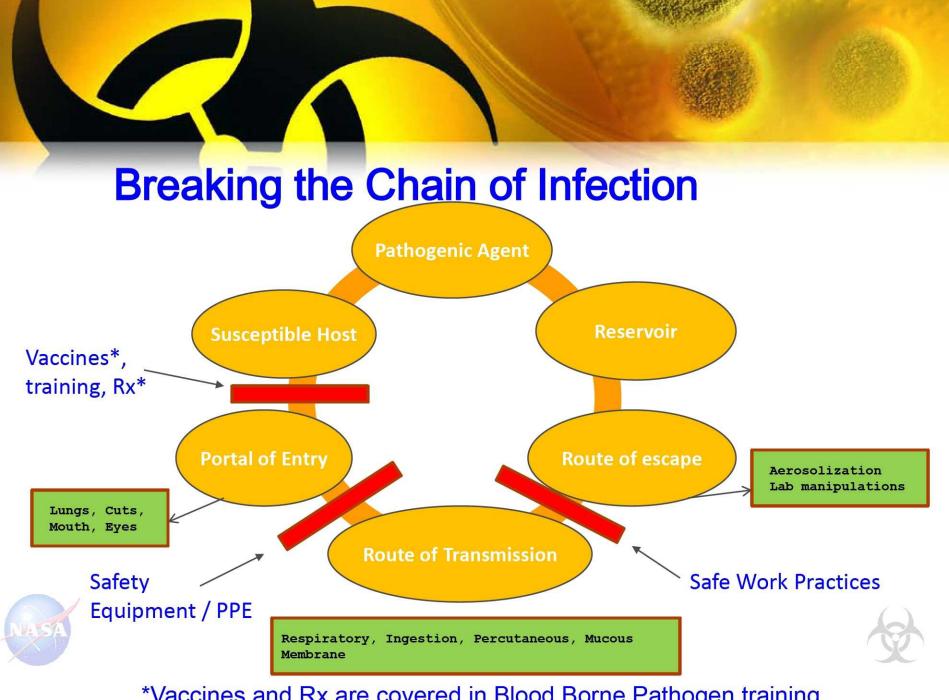




Essential Containment Components







*Vaccines and Rx are covered in Blood Borne Pathogen training.

Proper Biosafety Techniques

- Hands must be washed with soap and water frequently during the day - after removing gloves, when gloves are torn or damaged, after spills, and before leaving the laboratory.
- All procedures are performed carefully to minimize the production of splashes or aerosols.
- Keep disinfectants and spill supplies close at hand.
- Work surfaces are decontaminated at the completion of work or at the end of the day and after any spills.
- When working with sharps extra-care should be taken and sharps should be disposed of in a hard-walled closeable container.





- Organize and plan work procedures with safety in mind and keep an uncluttered work space.
- Eating, drinking, smoking, applying cosmetics, and lip balm and handling contact lenses are prohibited in the laboratory.
- Closed-toed shoes are required in the laboratories.





Biological Safety Cabinets (BSC)

- Biosafety cabinets are among the most effective and most commonly used primary containment devices when working with infectious agents.
- Biosafety cabinets complement careful work practices because aerosols can still escape the cabinet.

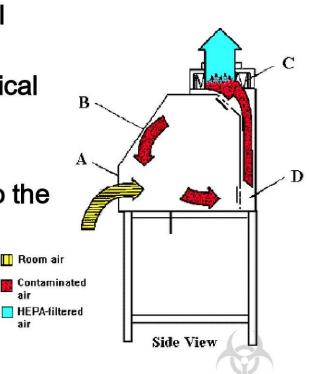




Biological Safety Cabinets (BSC)

Class I

- Provides personnel and environmental protection, but no product protection.
- It is similar in air movement to a chemical fume hood (+ HEPA filter)
- For BSL 1-3.
- All filtered air (100%) is exhausted into the lab or to the outside

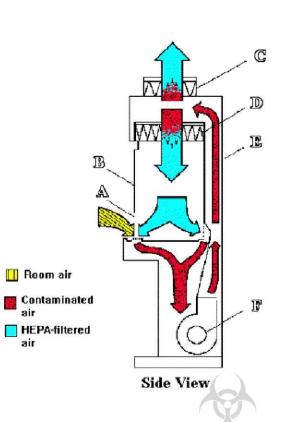




Biological Safety Cabinets (BSC)

- Class II Types A1, A2, B1 & B2
 - Provides personnel, environmental, and product protection.
 - For BSL 1-3.
 - Type A1 70% of air is recirculated –
 NOT ducted to building exhaust
 - Type A2 100% is exhausted ducted to building exhaust
 - Type B1 recirculates 30% of the air and exhausts 70%- ducted to building exhaust
 - Type B2 exhausts 100% of the air and ducted to building exhaust









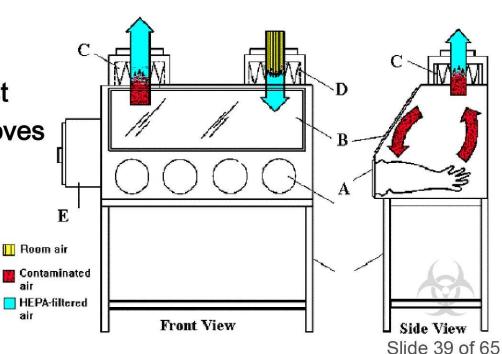




Slide 38 of 65

Biological Safety Cabinets (BSC)

- Class III
 - Provides maximum personnel and environmental protection. Also provides product protection.
 - For BSL-4.
 - Negative pressure.
 - Double HEPA exhaust
 - Heavy duty rubber gloves





Biological Safety Cabinets (BSC)

- Inward directional airflow is what protects you from the agents in the cabinet – Do not disturb it!
- Things that disrupt flow include
 - Sweeping sideways motion in the cabinet.
 - Repeated insertion and withdrawal of arms in and out
 - Opening and closing laboratory doors in the vicinity
 - Improper placement or operation of materials in the cabinet
 - Brisk walking past a BSC during use





Proper BSC Work Practices

- Check calibration and start-up BSC.
- Allow to run for 20 minutes to purge the air prior to working.
- Review procedure and plan your BSC layout – supplies, equipment, waste









Proper BSC Work Practices

- Disinfect cabinet and equipment going into cabinet.
- Do not place items over front grille, do not block back grille.
- Use plastic backed towels on work surface to absorb spills.







- Minimize movement of contaminated items over clean items (work from clean to dirty).
- Perform work 6 inches back of front intake grille.
- Clean items front, contaminated rear.
- Waste disposal area biohazard bags and disinfectant pans





Proper BSC Work Practices

- Do not use a flame. Turbulence and filter damage may occur.
- Equipment that causes turbulence (centrifuge, blender, etc.) should be placed in back 1/3 of work surface. All other work in the cabinet should stop while apparatus is running.
- Remove contaminated items only after sealed or decontaminated.
- Decontaminate after work is complete with appropriate disinfectant.



BSC Certification

- New/at least annually
- When moved
- After maintenance
- Maintenance should be performed by NSF-certified personnel





NOT A BSC!



Clean Bench -HEPA Filtered air blows into the employee's face

protecting the samples – not the employee









Ductless fume hood – Used for a variety of chemicals, but not for Biosafety.





Proper PPE Work Practices

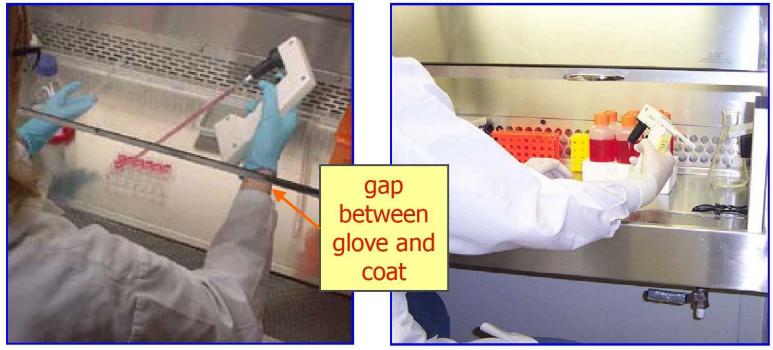
- Minimum PPE requirements for BSL-2 -
 - closed laboratory coat, one pair of gloves and closed-toed shoes
- Eye protection or splash guards in place for work that will produce aerosols.
- Wear PPE that is sized-properly.
- Don and doff gloves properly to prevent touching contaminated glove surfaces.





Proper PPE Work Practices glove and labcoat practices

Incorrect Correct









- Lockable doors (a must for restricted agents)
- Sink
- Bench tops/furniture impervious and easily cleaned
- Biological safety cabinet (if applicable)
- Eyewash/safety shower
- Inward airflow (desirable)





Aerosol Production

- Centrifuges Use only sealed rotors or cups
- Vortexing -
- Rocking/shaking
- Lyophilization
- Sonification
- Tissue Grinding
- Pipetting













Ring around the centrifuge!







Lyopholizer



- Never blow out last drop in pipette
- Use pipetting aids with filters
- Discharge liquid down side of container, using tip-to-wall contact
- Deliver as close as possible to contents





Vacuum Line Protection

- Fill flask with disinfectant to ensure that when flask is 2/3 full disinfectant concentration is sufficient
- Empty flask when flask is 2/3 full
- Place disinfectant trap in a secondary container
- Ideal plastic or plastic-coated flasks
- Label flasks with contents and NFPA diamond sticker







Autoclave

- An autoclave is a steam sterilizer that is used for biohazardous laboratory waste. In order to dispose of infectious laboratory waste (petri dishes, pipettes, culture tubes, glassware, etc.), the waste must be autoclaved for minimum of 15 minutes at 121°C (minimum 15 psi).
- The effectiveness of decontamination by steam autoclaving depends upon various loading factors that influence the temperature to which the material is subjected and the contact time.
- Particular attention must be given to packaging, including the size of containers and their distribution in the autoclave. Containers must be arranged in a manner that permits free circulation of steam.
- All processed items must have heat-sensitive tape, or other acceptable
 method (such as commercially available strips or vials of *Bacillus species*endospores or thermocouples), attached to confirm proper sterilization.
 Once the cycle has been completed, the waste can then be disposed of as
 medical waste.





Waste Disposal

- In lab keep closed!
- Use appropriate container Plastic bags/cardboard

 Red plastic bins are available for frozen items
- Do not over fill 2/3 rule must be able tie bags and close box
- Label box before putting in storage Name, date and Room #







Labels and Signs

- Warning labels shall be affixed: to containers of regulated waste; incubators, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials.
- Biohazard signs must be posted at entrances to all biosafety laboratories. The labels shall be fluorescent orange or orange-red or predominately so, with lettering and symbols in a contrasting color.
- An Emergency Action Plan must also be placed in each laboratory.





- Choose appropriate disinfectant and PPE
- Treat and allow to disinfect for specified time
- Dispose of all wastes including PPE in Biohazard
- Sharps Disposal plastic or cardboard container



Further information on disinfectant selection can be found at



Exposure / Spill Procedures

Needle sticks sharps incidence

- Notify supervisor
- Report to JSC Clinic for treatment

 If working with infectious agents, report any febrile illnesses to your supervisor.





Exposure / Spill Procedures

- Lab accidents survey
 - human error (65%)
 - equipment problems (20%)
 - unsafe acts (15%)
- Accident-prone:
 - ages 20-29
 - men > women





Spill Kits

Recommended kit contents-

- 1. gloves (several pairs)
- 2. Small disposable broom with dust pan, tongs, or forceps
- 3. Red medical waste bags
- 4. Disinfectant suitable for the biologically hazardous materials found in the lab (check expiration dates)
- 5. Germicidal gelling agent (optional)
- 6. Paper towels
- 7. Diking material or spill pillows for large spills(optional)
- 8.Instructions for spill clean-up







- DOMESTIC AND INTERNATIONAL SHIPMENT www.cdc.gov/od/ohs/biosfty/shipregs.htm
- SELECT AGENT TRANSFER TRACKING SYSTEM www.cdc.gov/od/ohs/lrsat.htm
- IMPORT AND EXPORT PERMITS FOR BIOLOGICAL MATERIALS

www.cdc.gov/od/ohs/biosfty/imprtper.htm

Organization specific protocols (examples: JSC 290/Wyle SHE-WLS-319)



IATA DGR training - specific to hazards being shipped



Recent Documented Exposures E.coli O157:H7, 2005, Spina et al, *J. Clin. Microbiology.*

- 4 lab workers in different diagnostic labs infected.
- Sudden increase in volume of specimens, low infectious dose, prolonged survival on stainless steel surfaces.
- Workers non-compliant with biosafety practices, including no gloves, hands were not washed as needed, open lab coats.





Recent Documented Exposures Select Agent Exposures, 2006-7, Texas A&M

- 2006: lab worker infected with Brucella melitensis
 - Was not authorized to work with the agent (Select Agent Program)
 - Infected after reaching into the Madison Chamber to clean it after aerosol work with B. melitensis
 - Infection was not reported for over a year to CDC
 - 2 months after infection, 3 other lab workers exposed to Coxsiella burnetti (Q fever), but were not reported.
 - July, 2007: CDC suspends research in SA lab





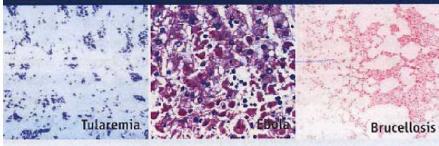
Science, Sept. 28, 2007



BIOSAFETY BREACHES

Accidents Spur a Closer Look at Risks at Biodefense Labs

Some Recent Exposures in U.S. Biodefense Labs



2002, 2003: E. coli 0157:H7 infections in two USDA labs

2004: Three workers infected with tularemia, Boston University

2004: Ebola needle stick (no infection), USAMRIID

2004: Anthrax exposure (no infection), Children's Hospital, Oakland, CA

2004: Valley fever (C. immitis) infection, Medical College of Ohio

2005: Potential Q fever exposure, Rocky Mountain Labs, Hamilton, MT

2006: Brucellosis infection, Texas A&M

